

The *2018 Annual Report of the Federal Select Agent Program* continues to provide insight into the regulatory activities of the Federal Select Agent Program (FSAP). The report includes a look at both the regulatory functions of the program, as well as compliance with the select agent regulations at laboratories across the nation. This annual report is FSAP's fourth report of aggregate program data, and reflects the program's ongoing commitment to transparency and increasing understanding of the program.

- FSAP is managed jointly by the Centers for Disease Control and Prevention's Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service's Agriculture Select Agent Services
- FSAP regulates the possession, use, and transfer of biological select agents and toxins (BSAT) so that important work with potentially dangerous and deadly pathogens is conducted as safely and securely as possible
- BSAT are materials that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products

253

ENTITIES WERE REGISTERED WITH FSAP

- 33%** ACADEMIC
- 17%** COMMERCIAL
- 15%** FEDERAL GOVERNMENT
- 29%** NON-FEDERAL GOVERNMENT
- 6%** PRIVATE

51% of entities were registered for Tier 1* BSAT

LAB BIOSAFETY LEVELS (BSL)

ENTITIES MAY HAVE MULTIPLE TYPES

- 30%** had BSL-2 and/or ABSL-2 labs
- 79%** had BSL-3 and/or ABSL-3 labs
- 3%** had BSL-4 and/or ABSL-4 labs

TOP REGISTERED AGENTS BY AGENCY

CDC's Division of Select Agents and Toxins

- Brucella melitensis*
- Brucella suis*
- Brucella abortus*
- Bacillus anthracis* (Pasteur strain)
- Francisella tularensis**

APHIS's Agriculture Select Agent Services

- Newcastle disease virus
- Avian influenza virus
- Ralstonia solanacearum*
- Xanthomonas oryzae*
- Brucella abortus*

COMPLIANCE & ENFORCEMENT

3 total entities participated in a corrective action plan (including **1** entity that newly agreed to participate in 2018)

0 total entities had fully suspended registrations (with **5** entities newly put under partial suspension in 2018)

9 matters were shared with the Federal Bureau of Investigation for potential investigation (FBI determined no action was needed in any of those cases)

4 entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services

THEFT, LOSS, OR RELEASE

0 thefts reported

8 reports of losses determined to be inventory accounting errors or inadvertent destruction of BSAT

0 occupational exposures resulting in illness, death, or transmission, out of the **185** incidents reported involving occupational exposures

TRANSFER APPROVALS: 192 DSAT | 61 AgSAS

26% of the transfers were from unregistered entities to registered entities, and occurred after the identification of BSAT in a diagnostic specimen or represented imports from outside the U.S.

206

TOTAL INSPECTIONS CONDUCTED BY FSAP

- 149** by DSAT
- 18** by AgSAS
- 39** joint DSAT & AgSAS

2.5

AVERAGE DURATION (IN DAYS) FOR INSPECTION

Range of **1** to **10** days

8,434

ACTIVE INDIVIDUAL SECURITY RISK ASSESSMENTS

Denied access for **24** individuals

KEY ABBREVIATIONS:

FSAP: Federal Select Agent Program **DSAT:** Division of Select Agents and Toxins **BSAT:** Biological select agents and toxins **ABSL:** Animal biosafety level
CDC: Centers for Disease Control and Prevention **APHIS:** Animal and Plant Health Inspection Service **AgSAS:** Agriculture Select Agent Services

*Tier 1 agent, those that pose the greatest risk through misuse